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Accordingly the above claims, which are dependent claims, are at least patentable for the reason of being dependent on an independent claim which is patentable.

Applicants note that the claims were indicated as meeting the criteria of PCT Article 33(2)-33(4) in the IPER issued by the European Patent Office (acting as IPEA).

Amended sheets as well as an amended claim set are attached hereto.

An allowance on the merits is respectfully requested.

Respectfully submitted, O. GLOBERMAN et al.

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June 12, 2003

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IN THE SPECIFICATION

1. Kindly replace the paragraph starting on page 2, line 13, with the following paragraph marked up to show changes made:

An aspect of some preferred embodiments of the invention is that a spacer having a first diameter is inserted and is then expanded to a second, much larger diameter. Preferably, the second diameter is greater than the first diameter by a factor of three, four, five or more. Thus, a spacer for an inter-vertebral space of a 12 mm height may be inserted using a needle having a 4 mm (inner) diameter. However, in some embodiments of the invention, a more modest diameter increase is achieved, for example, between 20% and 200% or 300%.

2. Kindly replace the paragraph starting on page 22, line 26, with the following paragraph marked up to show changes made:

The next step in the implantation method is preferably to close up the incision used to provide spacer 20, or, more typically, in a minimally-invasive procedure, to retract member 60 (Fig. 2B). In some preferred embodiments of the invention, the bone slurry may be injected with a needle after member 60 is removed, rather than while member 60 is still inserted.

3. Kindly replace the paragraph starting on page 48, line 16, with the following paragraph marked up to show changes made:

Fig. 5 illustrates a spacer 150 in which slits 152 are defined on the spacer in a spiral pattern. In this embodiment, spacer 150 may be expanded by applying a rotational force to the spacer, rather than an axial force. In a preferred embodiment of the invention, one end of the spacer is modified to grip bone, to provide a suitable anchor for bone, for example as exemplified by a pair of extensions 154. In a preferred embodiment of the invention, extensions 154 fold out, for example as shown by dotted line 156, to radially grasp the bone prior to the expansion of the spacer. Preferably, the extensions are made of an elastic or super-clastic material which is maintained in an axial configuration until the spacer is inserted in place. Such anchoring may also be useful for other embodiments of the invention, described herein. However, in other preferred embodiments of the



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invention, no bone anchors are provided, as the spacer can expanded in place without anchoring.

4. Kindly replace the paragraph starting on page 51, line 33, with the following paragraph marked up to show changes made:



Another advantage of lift-up spikes is the ability to provide a greater surface contact area (surface fill factor), which contact area can be smooth, rather than spiked.

CLAIMS

Sik 2

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1. (ORIGINAL) An expandable spacer, comprising:

an axial tube having a surface, a proximal end, a distal end and a length,

wherein, said surface defines a plurality of slits, said plurality of slits defining at least two axially displaced extensions, such that when said tube is axially compressed, said extensions extend out of said surface and define a geometry of an expanded spacer.

- 2. (ORIGINAL) A spacer according to claim 1, wherein said at least two axially displaced extensions comprises at least three extensions, which three extensions extend in at least three different directions from said tube.
 - 3. (ORIGINAL) A spacer according to claim 1, wherein said at least two axially displaced extensions comprises at least four extensions, which four extensions extend in at least four different directions from said tube.
 - 4. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are straight.
 - 5. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are curved.
 - 6. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are defined by a cut in said tube.
- 7. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are defined by a section removed from said tube.
 - 8. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are substantially parallel to said tube axis.
- 9. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are not parallel to said tube axis.
 - 10. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are arranged in pairs of same length.



- 11. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said slits are arranged in pairs of different lengths.
- 5 12 (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein slits associated with one extension axially overlap slits associated with a second, axially displaced, extension.
 - 13. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said proximal end of said tube defines a proximal end-cap, which end-cap extends outside of a volume defined by the geometry of said extended extensions.
 - 14. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said distal end of said tube defines a distal end-cap, which end-cap extends outside of a volume defined by the geometry of said extended extensions.
 - 15. (ORIGINAL) A spacer according to claim 13, wherein at least one of said extensions is flush with said proximal end of said tube.
- 16. (ORIGINAL) A spacer according to claim 13, wherein at least one of said extensions is flush with said distal end of said tube.
 - 17. (PREVIOUSLY AMENDED) A spacer according to claim 1, comprising at least one spur axially extending from said spacer, to engage tissue adjacent said spacer.
- 18. (ORIGINAL) A spacer according to claim\17, wherein said at least one spur comprises at least two spurs axially extending from said spacer.
 - 19. (PREVIOUSLY AMENDED) A spacer according to claim 1, comprising an inner bolt.
- 20. (ORIGINAL) A spacer according to claim 19, wherein said inner bolt has a smooth exterior.
 - 21. (ORIGINAL) A spacer according to claim 19, wherein said inner bolt has a threaded exterior.



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- 22. (PREVIOUSLY AMENDED) A spacer according to claim 19, wherein said bolt has a base, which base has an external diameter greater than an inner diameter of said tube, such that said base restricts axial motion of tube in one direction relative to the bolt.
- 23. (PREVIOUSLY AMENDED) A spacer according to claim 19, wherein said bolt has a head, which head locks against at least one end of said tube, to prevent axial expansion of said tube.
- 24. (ORIGINAL) A spacer according to claim 23, wherein said head is adapted to engage at least one protrusions extending from said tube toward said bolt head.
 - 25. (ORIGINAL) A spacer according to claim 23, wherein said head comprises at least one protrusions extending from said head toward said tube, to engage said tube.
 - 26. (ORIGINAL) A spacer according to claim 23, wherein said head comprises a flange, flared to have an outer diameter greater than an inner diameter of said tube.
- 27. (PREVIOUSLY AMENDED) A spacer according to claim 19, wherein said bolt is adapted to engage a pole element for holding said bolt during deployment of said spacer.
 - 28. (ORIGINAL) A spacer according to claim 27, wherein said bolt has an inner thread for engaging said pole element.
- 29. (ORIGINAL) A spacer according to claim 27, wherein said bolt mechanically engages said pole element as long as a head of said bolt is constrained by said tube.
 - 30. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises a plurality of segments, each segment defining one or more extensions that extend from said spacer.
 - 31. (ORIGINAL) A spacer according to claim 30, wherein said segments comprises at least two segment types, each segment type defining extensions that extend in different directions relative to said tube.

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- 32. (ORIGINAL) A spacer according to claim 31, wherein said two segment types comprises a horizontal segment defining two extensions that extend along a line and a segment defining four extensions that extend at about ±45° to said two extensions.
- 33. PREVIOUSLY AMENDED) A spacer according to claim 1, wherein an extension direction of at least one of said at least two extensions is normal to said tube.
- 34. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein an extension direction of at least one of said at least two extensions defines a sharp angle with said tube axis, in a plane containing said tube axis.
 - 35. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions does not extend along a direction perpendicular to said tube.
 - 36. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane containing said tube axis, a profile of a triangle, with the tip pointed away from said tube.
- 20 37. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane containing said tube axis, a curved profile.
 - 38. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane containing said tube axis, a profile that narrows and then widens, along a direction away from the tube.
 - 39. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a profile that narrows, along a direction away from the tube.
 - 40. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a profile that narrows and then widens, along a direction away from the tube.

- 41. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, in a plane perpendicular to said tube axis, a uniform profile.
- 42. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, a pointed top profile.
 - 43. (PREXIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, a top profile substantially the same size as a base of said extension.
- 10 44. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said at least two extensions has, a top profile substantially the larger that a base of said extension.
 - 45. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions are unevenly distributed along said axis.
 - 46. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions are evenly distributed along said axis.
- 47. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions are unevenly distributed along a circumference of said tube.
 - 48. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions are evenly distributed along a circumference of said tube.
- 25 49. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said different ones of said extensions have different geometries.
 - 50. (PREVIOUSLY AMENDED) A spacer according to claim\(\), wherein said extensions are distributed in a spiral pattern.
 - 51. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is coaxial with an axis of said expanded geometry.

- 52. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is parallel to an axis of said expanded geometry.
- 53. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is not parallel to an axis of said expanded geometry.
 - 54. (ORIGINAL) A spacer according to claim 53, wherein said tube axis and said expanded geometry axis are designed for oblique insertion of a spacer to be aligned, in its expanded state with vertebra.
 - 55. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer has an expanded geometry cross-section of a circle.
- 56. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer has an expanded geometry cross section of a rectangle.
 - 57. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a cross-section of said expanded geometry varies along an axis of said expanded geometry.
- 58. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a cross-section diameter of said expanded geometry varies along an axis of said expanded geometry.
 - 59. (ORIGINAL) A spacer according to claim 58, wherein said cross-section is rectangular and wherein said cross-sectional diameter increases along said expanded geometry axis.
 - 60. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a cross-section diameter of said tube varies along an axis of said tube.
- 61. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a cross-section of said tube varies along an axis of said tube.
 - 62. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube has a circular cross-section.

- 63. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube has an elliptical cross-section.
- 64. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube has a rectangular cross-section.
 - 65. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is bent, when the spacer is unexpanded.
- 10 66. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is straight when the spacer is unexpanded.
 - 67. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is bent when the spacer is expanded.
 - 68. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube axis is straight when the spacer is expanded.
- 69. (PREVIOUSLY AMENDED) A spacer according to claim 1, comprising a ratchet mechanism to maintain said spacer in an expanded configuration.
 - 70. (PREVIOUSLY AMENDED) A spacer according to claim 1, comprising at least one portion of said spacer that prevents axial contraction of said spacer.
- 25 71. (ORIGINAL) A spacer according to claim 70, wherein said at least one portion comprises a pair of tabs that abut when the spacer is axially contracted.
 - 72. (ORIGINAL) A spacer according to claim 70, wherein said at least one portion comprises a strip that folds and forms a thickness between two opposing sides of said spacer, preventing the opposing sides from meeting.
 - 73. (CURRENTLY AMENDED) A spacer according to claim 1, comprising at least one protrusion on at least one of said extensions, to prevent collapsing of said extension.



- 74. (CURRENTLY AMENDED) A spacer according to claim 1, comprising at least one protrusion on at least one of said extensions, to interlock said two extensions.
- 75. (PREVIOUSLY AMENDED) A spacer according to claim 1, comprising at least one interconnecting element for interconnecting said extensions when the extensions are expanded.
 - 76. (ORIGINAL) A spacer according to claim 75, wherein said interconnecting element comprises a flexible wire.
- 77. (ORIGINAL) A spacer according to claim 75, wherein said interconnecting element comprises a substantially rigid strut.
 - 78. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises only bending joints.
 - 79. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises at least one twisting joint.
- 80. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises a lift-up-extension in which a significant axial section of the tube is lifted away from said tube to form said expanded geometry.
 - 81. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises at least two legs that are coupled by a extension top.
 - 82. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises at least three legs that are coupled by a extension top.
- 83. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions comprises at least four legs that are coupled by a extension top.
 - 84. (PREVIOUSLY AMENDED) A spacer according to claim 1 wherein at least one of said extensions comprises at least two legs, which legs are aligned with the tube axis.

- 85. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a plurality of annealed locations are provided on said spacer to assist in expansion of said spacer.
- 86. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a plurality of etched locations are provided on said spacer to assist in expansion of said spacer.
 - 87. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein a plurality of holes are provided on said spacer to assist in expansion of said spacer.
- 10 88. (ORIGINAL) A spacer according to claim 87, wherein said holes distribute stress in said spacer.
 - 89. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is annealed as a unit.
 - 90. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises means for changing the axial length of the spacer over time, after the spacer is implanted.
- 20 91. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is formed of metal.
 - 92. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is formed of plastic.
 - 93. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is formed of a combination of distinct zones of different materials.
- 94. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises an elastic material, which is elastically deformed by the extension deformation.
 - 95. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises a plastic material, which is plastically deformed by the extension deformation.

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- 96. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises a super-elastic material, which is super-clastically deformed by the extension deformation.
- 5 97. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer comprises a shape-memory material.
 - 98. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to be axially deformed under axial pressures of over 20 Kg.
 - 99. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to be axially deformed under axial pressures of over 30 Kg.
- 100. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to be axially deformed under axial pressures of over 50 Kg.
 - 101. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to be axially deformed under axial pressures of over 70 Kg.
- 20 102. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to be axially deformed under axial pressures of over 90 Kg.
 - 103. (CURRENTLY AMENDED) A spacer according to claim 1, wherein said spacer is adapted to remain expanded in a vertebra of an active human, when placed with the tube axis perpendicular to a spine of said human.
 - 104. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube has a cross-sectional diameter smaller than 2 times the maximal cross-sectional diameter of said expanded geometry.
 - 105. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said tube has a cross-sectional diameter smaller than 4 times the maximal cross-sectional diameter of said expanded geometry.

106. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said expanded geometry is sized to fit between two human vertebrae.

107. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions have tips and wherein said tips has a surface fill factor of at least 20% relative to the contact surface of a target vertebra with the spacer geometry.

108. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions have tips and wherein said tips has a surface fill factor of at least 40% relative to the contact surface of a target vertebra with the spacer geometry.

109. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions have tips that contact a surface of target vertebra and wherein said tips has a surface fill factor of at least 60% relative to the contact surface of the target vertebra with the spacer geometry.

110. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said expanded geometry covers at least 40% of the surface of a target vertebra, previously contacting a disc.

111. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said expanded geometry covers at least 60% of the surface of a target vertebra, previously contacting a disc.

112. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said expanded geometry covers at least 80% of the surface of a target vertebra, previously contacting a disc.

113. (ORIGINAL) A spacer, comprising:

an elongate body having a surface and having a maximum cross-section at a portion thereof; and

a plurality of at least two axially displaced extensions radially extending from said body,

wherein, said extensions are axially dense on at least 40% of said body, including said portion, such that at least 50% of a surface area of said body is covered by extensions, wherein said dense extensions define a cross-section having a diameter at least two times a diameter of said body cross-section and wherein said extensions are formed of said surface.

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- 114. (ORIGINAL) A spacer according to claim 113, wherein said extensions are dense on at least 50% of said body.
- 115. ORIGINAL) A spacer according to claim 113, wherein said extensions are dense on at least 70% of said body.
 - 116. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is coated with a bio-active coating.
- 10 117. (ORIGINAL) A spacer according to claim 116, wherein said bio-active coating retards bone ingrowth.
 - 118. (ORIGINAL) A spacer according to claim 116, wherein said bio-active coating promotes bone ingrowth.
 - 119. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said extensions comprises spikes.
- 120. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein an extensions
 designed to carry greater stress has an increased strength over another extension.
 - 121. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer has an angular orientation.
- 25 122. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least two of said at least two extensions are designated to hold apart two verteurs.
 - 123. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein said spacer is lordotic.
 - 124. (PREVIOUSLY AMENDED) A spacer according to claim 1, wherein at least one of said extensions is adapted to embed in vertebral bone.